October 29, 2010 Letter to Jessica Sanders

Exhibit 171

From: Kristen Barnes
To: JESSICA.B.SANDERS@CMS.HHS.GOV
Cc: Christopher Mucke
Subject: RFQ526473 - ACLR Medicare Part D Recovery Audit Capability Statement
Date: Friday, October 29, 2010 12:29:26 PM
Attachments: ACLR Medicare Part D Recovery Audit Capability Statement (2).pdf

Dear Ms. Sanders,

Please find attached our capability statement for Medicare Part D Recovery Audit Program.

Please confirm receipt of this e-mail and let us know if you have any questions.

Thank you for your time,

Kristen Barnes
ACLR, LLC
1100 Circle 75 Parkway, Suite 960
Atlanta, GA 30339

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ACLR *Strategic Business Solutions*

550 Forest Avenue
Suite 15-2
Plymouth, Michigan 48170
Ph 734 207 0404 Fx 734 207 0410

October 29, 2010

Submitted Via Email to: JESSICA.B.SANDERS@CMS.HHS.GOV

Jessica Sanders
Department of Health & Human Services
Centers for Medicare and Medicaid
7500 Security Blvd; M/S C2-21-15
Baltimore, MD 21244

Re: Sources Sought Notice: RFQ526473
Recovery Audit Services in Support of Medicare Part D

Dear Ms. Sanders:

Thank you for the opportunity to submit a Capability Statement for the Recovery Audit Services in Support of Medicare Part D sources sought notice. The following contains our response as well as other related information you may find pertinent to your request.

ACLR has teamed with Allpro/Staffnet, LLC, a Service Disabled Veteran Owned Small Business and GSA Schedule holder. Allpro/Staffnet is a healthcare staffing service provider with access to physicians, nurses, and other qualified medical personnel including Medicare Part D benefit plan actuaries, medical coders and billers, and pharmaceutical personnel throughout the country. We believe this teaming arrangement provides for the rapid development of a highly qualified national recovery team that can quickly and efficiently develop and implement a proven and effective national recovery audit program for Medicare Part D.

Please let me know if I may be of any further assistance. I can be reached at 734-207-0404, my cell at 248-924-1964, or via email at cmucke@aclrsbs.com. Alternatively, I may be reached through my assistant, Kristen Barnes at 770-857-1014. Thank you for your consideration.

Very truly yours,

Christopher A. Mucke, CPA
Managing Principal

CAPABILITY STATEMENT
ACLR STRATEGIC BUSINESS SOLUTIONS

CORE COMPETENCIES:

ACLR is a proven national recovery auditor with core competencies in:

- Designing, implementing, and managing multiple national recovery audits.
- Developing recovery audit processes and procedures derived from the best practices of the nation's largest and most respected companies and government agencies.
- Data mining and management, statistical sampling, predictive modeling, and improper payment estimation, and collection.
- Researching, analyzing, and interpreting varied federal, state, and local laws and applying conclusions to transactional data.
- Maximizing stakeholder input to achieve accurate results while reducing the administrative burden of complying with federal and state law.
- Leveraging project staffing models to provide clients with balanced project teams that maximize recoveries at significantly reduced costs.
- Developing knowledgeable and efficient audit professionals dedicated to achieving accurate results and maximizing client returns.
- Developing innovative solutions to an ever adaptive business environment and the increasing efficacy of fraudulent and abusive tactics.
- Developing and implementing comprehensive transactional audit and sampling methodologies designed to maximize efficiencies and recoveries.

PAST PERFORMANCE:

The following is a listing of national recovery audit projects engaged in by ACLR, LLC:

Ford Motor Company:

Project: Multistate Audit Management Services

Provided national recovery audit services including legal representation/expert testimony of indirect tax issues, which consisted of:

- Designing statistical sampling methodologies based on varying federal, state, and local laws, regulations, and auditor preference.
- Reconciling transactional data containing millions of records to company ledgers, journal entries, accounts of record, and other detailed source documentation to verify transactional data integrity, completeness and accuracy.

- Developing evidence to support contentions in protests and appeals and providing testimony in court and/or to administrative law judges as required.

- Developing predictive models to identify target data populations consisting of high incidences of improper payments.

Project: Bad Debt Recovery

Provided national recovery services for improper payments associated with financial contract bad debt write-offs, which consisted of:

- Quadrupling recoveries identified by major accounting firms while identifying, documenting, and supporting the claims in a fraction of the time.

- Developing position papers based on federal, state, and local contract and tax law to support recovery contentions.

- Reconciling transactional data for bad debt related contracts through total contract receivables and company ledger totals.

Contact:	Chris Hall; Director	Contact:	Dave Davis; Manager
Number:	313-337-3413	Number:	678-893-8552
Email:	chall58@ford.com	Email:	ddavi298@ford.com

General Electric Company:

Project: Multistate Audit Management Services

Provided Sarbanes-Oxley compliant process mapping and recovery audit procedures and assisted in the reduction of improper payment liabilities, which consisted of:

- Mapping pre-recovery audit processes and developing matrices to enhance identification and recovery of improper payments.

- Researching multiple state and local tax laws and obtaining evidence to support contentions in numerous state audit appeals.

- Developing training manuals and training internal accounting personnel in recovery audits.

Contact:	Patrick McWilliams; Manager	Contact:	Thais Thompson; Analyst
Number:	281-584-5059	Number:	678-844-5446
Email:	mcwilliams.patrick@corp.sysco.com	Email:	thais.thompson@ge.com

Will Yancey:

Project: Medicare Sampling Support Services

Provided statistical sampling support services on samples generated by Program Safeguard Contractors/Zone Program Integrity Contractors that resulted in the identification of sampling anomalies associated with:

- Not achieving pre-defined precision and confidence intervals.
- Not verifying payment of claims and the lack of underpayment/recoupment offset.
- Not identifying and analyzing outliers for possible extrapolation distortion.
- Failing to document non-sampling errors arising from the incorrect application of CMS Medicare policy and policy changes, data extraction errors, and the lack of complete evidentiary consideration for medical review decisions.

Contact: Will Yancey, Ph.D.; This company has since been acquired by ACLR.

The following is a listing of projects performed by Allpro/Staffnet, LLC:

Allpro/Staffnet:

Project: Medical Staffing Services

Providing healthcare professionals to Department of Veteran Affairs' medical centers throughout the country including:

- Medical Supply, Billing, and Coding Clerks
- Nursing Staff & Certified Nurse Assistants
- Operating Room Technicians.

Contact: Ray Baker
Address: Memphis, Tennessee
Number: 901-522-7221

Contact: Sharon Dennison
Address: Mount Home, Virginia
Number: 432-926-1171

Contact: Fernando Rios
Address: Louisville, KY
Number: 502-287-4000

Contact: Denise Vialpando
Address: Cheyenne, WY
Number: 307-778-7550

DIFFERENTIATORS:

The two most differentiating characteristics of ACLR is our attention to detail and focused efforts on efficiently achieving accurate results. In addition, ACLR audit professionals have extensive and varied industry experience coupled with intense contractual, legal, and statistical analysis expertise derived from some of the country's most successful and well respected companies. This yields a unique service offering that includes:

- Fully qualified and experienced recovery auditors providing
  - Vast knowledge of recovery audit best practices from multiple fields and industries,
  - Research, analysis, and application of ever-changing federal, state, and local law, regulations, and rulings to contractual agreements in a varied and multi-transactional environment,
  - Extensive experience with industry accounting systems such as SAP, PeopleSoft, and Oracle as well as many proprietary systems, and
  - An extensive internal training regimen that yields interns as experienced as that of other firms' senior staff.
- A focused and driven small business that regularly achieves superior results to that of its larger competition while simultaneously reducing the workload of clients and other stakeholders.
- Dedicated, state of the art computers and servers and current recovery audit applications including RATSTATS, ACL, CART, Adobe, and the Microsoft suite of products.
- An extensive library of Sarbanes-Oxley compliant processes and procedures encompassing data management, mining, and analysis, reconciliation, sampling, and recovery audit.

This translates into a Medicare Part D recovery audit program that includes:

- The fast and efficient development and implementation of multiple and comprehensive audit strategies, approaches, and documented work processes.
- Finalizing initial audits of 1,500 - 1,700 plan sponsors to quantify improper payments such that CMS can mitigate improper payments occurring in Medicare Part D back through the inception of the program as permitted under 42 CFR 423.346(b).

RESPONSE REQUIREMENTS:

1. Demonstrate experience and/or knowledge in performing recovery audits on a national basis.

   As identified under "*Past Performance*" above, ACLR professionals have conducted and managed multiple national recovery audits for numerous large companies. For example, ACLR managed the indirect tax audit process for Ford Motor Company. This project required the generation of samples from datasets in excess of tens of millions of transactions containing hundreds of individual data fields as well as managing over 500 state and local tax audits annually on behalf of Ford Motor Company and related companies. For this and all national recovery projects conducted on behalf of General Electric Company, Ebix, and Koch Industries, ACLR professionals researched, interpreted, and applied thousands of statutes, regulations, and applicable rulings in each of the 50 states, the District of Columbia, Puerto Rico, and over 1250 local jurisdictions.

   ACLR also provided statistical sampling support services to Will Yancey Ph.D., an expert in Medicare statistical sampling. These projects required the review of statistically sampled audits for many Medicare providers. During the provision of these services, ACLR professionals identified

several audits that contained violations of generally accepted statistical sampling principles for audits and the Medicare Program Integrity Manual, which ultimately prevailed at trial.

During these and other similar projects, ACLR professionals:

- Developed comprehensive, Sarbanes-Oxley compliant, national recovery audit processes and procedures.
- Developed predictive models to target suspected overpayment populations for detailed or sampled reviews and designed statistical sampling methodologies meeting parameters of varying federal and state jurisdictional requirements.
- Reconciled transactional data containing hundreds of millions of records to company ledgers, journal entries, accounts of record, and other detailed source documentation to verify transactional data integrity, completeness and accuracy.
- Developed evidence to support contentions in protests and appeals and provided testimony in court and/or to administrative law judges as required.

2. Demonstrate an understanding of the Medicare Part D program to sufficiently devise a plan for identifying and recovering improper payments.

Medicare Part D is a federal program designed to provide prescription drug cost assistance for Medicare beneficiaries. This program is predicated on the use of plan sponsors who pay a portion of prescription drug costs on behalf of these beneficiaries and who are compensated by Medicare beneficiaries through premiums and by the federal government. Federal government payments to plan sponsors consist of monthly estimated payments based on approved plans and annual reconciling payments designed to ensure the sharing of risk. This annual reconciling payment is based on an offset of estimated payments, and actual plan expenses including drug expenditures and true out-of-pocket (TrOOP) expenditures of beneficiaries. The annual reconciling payment is also net of administration costs and direct and indirect remuneration (DIR), which includes any discounts, rebates, and other price concessions that plan sponsors may receive from drug manufacturers or other sources.

Due to the nature of program payments and the use of estimated monthly "pre-payments", improper payments in Medicare Part D ultimately occur when the annual reconciling payments are made to plan sponsors. As these reconciling payments are based in part on actual plan costs as submitted through prescription drug event (PDE) data, improper payments through the Medicare Part D program can occur through a variety of circumstances and arise through errors made by plan sponsors, beneficiaries, prescription plan managers, pharmacies, and healthcare providers.

ACLR can devise a national recovery audit plan for Medicare Part D that includes:

- Automated and detailed reviews of PDE data to identify anomalies such as duplicates, the inclusion of CMS or plan formulary excluded drugs, inaccurate prescriber identifiers, and improper sales tax. These automated reviews may also be conducted on a multi-plan sponsor basis to ensure that adequate reflection of beneficiary and concomitant TrOOP data on plan transfers.

- Plan sponsor audits that:
    - Verify the accuracy of PDE data submissions against point of sale and other plan data in accordance with generally accepted statistical sampling audit procedures and the Medicare Program Integrity Manual.
    - Verify the veracity of PDE submissions against plan sponsor accounting data such as ledgers, journal entries, invoices, and other accounts payable and receivable data.
- The reconciliation of available actual DIR data against estimated DIR data to identify, or ascertain its value in identifying, improper payments.

3. Demonstrate experience and/or knowledge of recovery audit activities performed on other public or commercial pharmacy benefit programs.

   Pharmacy benefit plans are insurance programs designed to lower prescription costs for beneficiaries. These plans consist of formularies that typically consist of items such as cost sharing thresholds for generic, brand name, and specialty medications; pre-authorization of specifically named drugs; and the use of mail order pharmacies to obtain maintenance drugs. While most plans offer more favorable benefits, plans must provide standard benefits which outline varying deductibles, coinsurance rates, and catastrophic coverage limits.

   ACLR professionals have performed national recovery audits on insurance plans for automobile, major appliances, aircraft engines, and electrical equipment warranties. To support identified recoveries, ACLR professionals were required to analyze plan terms and conditions to ensure that premiums and/or underlying costs were strictly applied according to varying state and local law. These reviews included obtaining supporting documentation, such as equipage and service invoices, and applying this source documentation to plan terms and conditions to support recovery contentions.

   Similarly, ACLR professionals can conduct exhaustive reviews of individual pharmacy benefit plans to ensure strict adherence of submitted PDE information to benefit plan criteria to;

   - Demonstrate compliance of PDE data to plan formularies.
   - Demonstrate that beneficiary payments are commensurate with plan requirements.
   - Ensure that TrOOP expenses do not include costs such as drugs not listed on the plan formulary, foreign sourced drugs, over the counter drugs, and other prohibited costs.

4. Demonstrate experience and/or knowledge of data mining and analysis and how it could be adapted to support Medicare Part D recovery audits.

   As identified previously, ACLR professionals have extensive experience working with copious amounts of transactional data similar to the PDE universe. These data elements often included hundreds of fields for each individual transaction. In a sales and use tax environment, intimate knowledge of each transaction is required. At a minimum, this knowledge requires an understanding of what was purchased, how and where it was used in business processes, the assignment of costs on the attendant invoice, and how state and local tax law applies. Managing these knowledge requirements against the millions of transactions that occur on a daily basis for each of our clients requires an intense understanding of data mining and management, sampling methodologies and

predictive modeling, verification of data completeness and accuracy, and data workflow and materiality. In addition, managing these knowledge requirements also requires the ability to adapt internal processes and procedures to the varying internal accounting and data management processes and procedures of each of our clients.

In the Medicare Part D program, plan sponsors submit PDE data to CMS on a recurring basis. These PDE submissions consist of data elements that are quantifiable, verifiable, and auditable. Analyzing these data elements consists of an initial review to ascertain the veracity of data face value, a more comprehensive data review to identify anomalies, and a final review involving auditing plan sponsors.

Data Review & Verification:

Improper payments are defined by the Office of Management & Budget (OMB) as including any payments made "as a result of insufficient or lack of documentation". Strict adherence to this statement requires that each PDE data element has been properly submitted according to listed field values and supporting prescriber, beneficiary, National Drug Code, and other databases.

Once populated, data management systems have the capability to analyze individual data elements and generate reports of improperly submitted PDEs, which can be returned to individual plan sponsors (or their benefit plan managers) for review and resubmission on a detailed or sampled basis as required by CMS. Any remaining insufficiently documented PDEs resulting from these detailed or extrapolated sample reviews would result in improper payment and used to identify audit targets. The types of items reviewed during this stage would include:

- Validating and matching such fields as Service Provider Identifiers and submitted Health Insurance Claim Number (HICN) numbers to National Provider Identifier (NPI), Medicare HICN, Social Security Administration, or other similar databases,

- Validating that Product/Service Identifier submissions match the National Drug Code 11 format and listing.

Comprehensive Data Review:

The secondary data review process consists of conducting more comprehensive reviews on multiple PDEs and PDE data elements. These reviews would consist of such items as;

- Identifying duplications of beneficiary or prescriptions as well as other anomalies within individual plans and throughout all plan sponsor PDE data.

- Demonstrating whether multiple beneficiary prescribed medications meet standardized drug regimens.

- Analyzing peer and/or regional prescribing trends or NPI with specialty tier drugs to identify anomalies such as overprescribing or prescribing drugs outside of typical provider type capabilities to identify areas of potential fraud and abuse.

- Identifying other miscellaneous improper payments such as improperly calculated sales taxes.

Plan Sponsor Audits:

The small plan sponsor population lends itself to multiple audit selection possibilities including the audit of each plan sponsor on an annual or multiyear basis. Typically, audits of populations similar to PDE data submissions employ statistical sampling methodologies to select events to review. In accordance with the Medicare Program Integrity Manual and/or other CMS requirements, samples can be drawn from individual plan sponsor PDE data and audited against point of sale and other plan data to verify the veracity of the submissions and extrapolate errors across the population. These types of audits could verify that:

- PDE submissions are reflective of actual costs as recorded on the plan sponsor's books and records.
- Point of sale data matches PDE data submissions.
- Prescriptions were accurately filled and that beneficiary co-payment amounts were paid according to plan formularies.
- Beneficiary TrOOP expenses were accurately calculated according to CMS and plan requirements.
- Cost data (negotiated prices) are accurate and does not include disallowed costs.

Plan sponsor audits can also:

- Include reconciliation of actual DIR data to estimated amounts provided.
- Be used to calculate individual plan sponsor "effective error rates" on differences between PDE submissions and point of sale and other plan data, which may be used by CMS to more accurately calculate actual plan cost data during the bid process and in the year-end reconciliation process.

5. Demonstrate experience and/or knowledge of the Medicare Advantage Prescription Drug (MA-PD) program and Medicare Advantage Prescription Drug Plans (MA-PDP).

The MA-PD program is designed to permit Medicare beneficiaries to receive Medicare Parts A, B, and D benefits from private insurers rather than through the traditional Medicare program. Under this program, private health insurers attract members by offering MA-PDP that contain a variety of Medicare services including other services that may not be available under traditional Medicare in addition to offering varying levels of member cost sharing. Typically, MA-PDP vary on monthly premium amounts paid by enrollees that are offset by increased or decreased co-payments for various service offerings such as hospitalization, inpatient surgery, and dental coverage including varying co-payments for generic drugs and changes in annual out-of-pocket limits.

MA-PDP are reimbursed by monthly premiums paid by enrollees, directly or through a social security payment withholding, and by Medicare. The monthly premiums paid by Medicare are set at capitated amounts on a per-enrollee basis. To receive these premiums, insurers transmit data about their enrollees to Medicare. This data contains information related to enrollments and disenrollments, plan benefit package and plan changes, updates, and any corrections related to Medicaid or other institutional required information. This information is validated against information contained in

Social Security Administration and Railroad Retirement Board databases as well as other CMS data systems to validate the accuracy of payment calculations. Payments made by Medicare may also be retroactively or prospectively adjusted. These adjustments are based on the demographic or health status of the enrollee. Once payments have been calculated for each enrollee, the payments plus any adjustments, subsidies, and penalties are summarized at the plan level and paid to the insurer.

BUSINESS INFORMATION:

Requested business information is as follows:

DUNS:		780272873	829975270
Company Name:		ACLR, LLC	Allpro/Staffnet, LLC
Company Address:	Street	550 Forest Avenue, Suite 15-2	295 Plus Park Blvd., Suite 108
	City, State Zip	Plymouth, MI 48170-3793	Nashville, TN 37217
Business Contact:	Name	Kristen Barnes	Louis Tapia
	Phone Number	770-857-1014	615-216-0356
	E-Mail	kbarnes@aclrsbs.com	louis.tapia@allprostaffnet.com
Business Type:	Type	Small Business	Service-Disabled Veteran Owned Small Business
	GSA Schedule	GS-23F-0074W	V797P7147A
	Cage Code	5QKV2	5GXG6
Verification Contact:	Name	Christopher Mucke	Louis Tapia
	Phone Number	734-207-0404	615-216-0356
	E-Mail	cmucke@aclrsbs.com	louis.tapia@allprostaffnet.com

Additional information for ACLR may be found at www.aclrsbs.com and www.willyancey.com and for Allpro/Staffnet at www.allprostaffnet.com.

Excerpts from the Deposition of Rosalind Abankwah

Exhibit 172

IN THE UNITED STATES COURT

OF FEDERAL CLAIMS

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ACLR, LLC

Plaintiff,

-vs- Civil Action No. 16-309

THE UNITED STATES (Judge Campbell-Smith)

Defendant.

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Thursday, September 14, 2017

Baltimore, Maryland

THE DEPOSITION OF ROSALIND MICHELLE ABANKWAH

The deposition of ROSALIND MICHELLE ABANKWAH was taken on Thursday, September 14, 2017, commencing at 1:04 p.m., at the Department of Health and Human services, Office of General Counsel, 7500 Security Boulevard, Central Building, Baltimore, Maryland, before CHERYL NICHOLSON, CCR, CLR, Stenotype Reporter and Notary Public in and for the State of Maryland.

more than million -- a million dollars and Minnesota might be more but we'll have to run the numbers to see.

So I was like, okay, run the numbers, because that's part of what they do. But when Louisiana fizzled out, it was like, oh, my goodness, why even bother with Minnesota. So there was an issue with Minnesota. Minnesota had -- Minnesota had a -- some kind of fee or something -- I don't remember the name of it. They had something that was quirky and -- yeah.

And then with the fact that the guy in CM, the policy guru, let me know you cannot recover based on what's in that sales tax field, it didn't matter what Minnesota did; it's not going to be recoverable.

Q. So that somebody at CM told you that you couldn't -- that CMS wasn't going to pursue the Minnesota sales tax --

A. That we should not look at anything in the sales tax field as potential recovery -- for potential recovery.

Q. Even in Minnesota?

A. Even in Minnesota.

Q. And that was at or about the same time he told you with Louisiana?

A. Yes. That would have been after Louisiana. Because we were thinking, okay, do you mean just up to 10 cents, because there were dollar amounts above 10 cents, and that's when he said, no, any dollar amount in that sales tax field is not recoverable.

Q. And what was his name?

A. Craig Miner.

Q. So after you had that conversation about Minnesota with Mr. Miner, then what did you tell the NBI MEDIC about their work on Minnesota?

A. I told them and I told my managers and all we need to not look at Minnesota, we need to resolve Louisiana and not look or pursue Minnesota.

Q. And what was left to be resolved with Louisiana at that point?

A. At that point I believe --
Q. Was that just that the payments they give back to the sponsors that had paid?
A. Uh-huh. And figure out which ones hadn't and to tell them don't do it.
Q. So the Minnesota sales taxes were never pursued by the NBI MEDIC?
A. To the extent that that they did some analysis, but to the extent that CMS would have sent a letter out, no, we did not.
Q. And the decision was made with Minnesota, I think you said, in early 2015?
A. Yes.
Q. Was there anything with any other states --
A. No.
Q. -- on the sales tax issue?
A. No. As far as I know, it was just Louisiana and then Minnesota. Nothing else.
Q. I should be more clear. Was the NBI MEDIC examining any other states other than Louisiana and Minnesota for a potential sales

NBI MEDIC's June 2015 Update for Deleted Prescription Drug Event for Louisiana Sales Tax Project

Exhibit 173

Unallowable Sales Tax Payments Vulnerability

June 2015 Update for Deleted Prescription Drug Event Records for the Louisiana Sales Tax Project HITS # 29897

National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC)

Prepared for:
The Centers for Medicare & Medicaid Services

Task Order:
HHSM-500-2005-0001I-0001, Mod 26

October 23, 2015

Executive Summary

States are prohibited under 42 C.F.R. § 423.440 (codifying the statutory preemption of State law at section 1860D-12(g) of the Social Security Act [42 U.S.C. § 1395w-112(g)])[1] from imposing a premium tax, fee, or other similar assessment for:

> any payment CMS makes on behalf of Part D Plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D Plans by a beneficiary or by a third party on behalf of a beneficiary.

A state sales tax is different from a premium tax and is not prohibited by the federal statute. States have varying laws addressing state and local sales taxes and most states prohibit the application of a sales tax at both a state and local level to Medicare prescription drugs.

For example, Louisiana statute specifically exempts prescription drugs purchased through or pursuant to Medicare Part B and Part D from the sales and use taxes imposed by any local governmental subdivision, school board, or other political subdivision whose boundaries are not coterminous with the state.

In Health Plan Management System (HPMS) memo guidance dated August 13, 2010,[2] September 1, 2010,[3] December 21, 2010,[4] and April 11, 2011,[5] plan sponsors were notified of the unallowable sales tax issue, with respect to the Louisiana State Constitution of 1974, Article VII: Revenue and Finance, §2.2(B)(3), where it is written : "Effective July 1, 2003, the sales and use tax imposed by the state of Louisiana or by a political subdivision whose boundaries are coterminous with those of the state shall not apply to sales or purchases of the following items:…(3) Prescription drugs.". At that time, plan sponsors were instructed to recoup any sales taxes paid on 2010 Part D prescription drugs in Louisiana, resubmit corrected PDE records for the affected transactions and reimburse any sales taxes paid by beneficiaries, and to take

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[1] Section 1860D-12(g) of the Social Security Act, titled "Prohibition of State Imposition of Premium Taxes; Relation To State Laws," states: "The provisions of sections 1854(g) and 1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C."

[2] http://cms.hhs.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoLASalesTax_081310.pdf

[3] Centers for Medicare & Medicaid Services, "Revised Notice to Part D Sponsors Operating in Louisiana," Health Plan Management System memorandum, U.S. Dept. of Health and Human Services, September 1, 2010

[4] http://cms.hhs.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoLASalesTaxRecoupment_122110.pdf

[5] http://cms.hhs.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoLASalesTax_041111.pdf

immediate steps to ensure that no further sales taxes were paid on Part D Louisiana pharmacy claims. Matters concerning the unallowable sales tax payments made by Medicare Part D were referred to the Health and Human Services/Office of Inspector General (HHS/OIG) in 2009, and, as a result of the case referral, two civil actions were imposed resulting in a recovery of more than $3.8 million.

As a result of the successful outcome and recoveries made regarding the Louisiana case referral, the NBI MEDIC conducted a probe analysis in September 2014 to determine if this issue had resurfaced and plan sponsors were complying with CMS guidance. This initial data analysis revealed Medicare Part D payments included sales taxes in the amount of $208,851,252 for all states during the period of January 1, 2011-August 31, 2014. Of this amount, $739,107 were related to payments made for sales taxes in Louisiana during the initial analysis.

Based on these results, the NBI MEDIC determined that program vulnerability exists, plan sponsors are continuing to allow improper payments for unallowable sales tax despite CMS guidance, and further review is warranted.

Background

In December 2014, CMS notified plan sponsors to both recoup payment for any sales taxes inappropriately paid on Medicare Part D prescriptions in Louisiana and to instruct the plan sponsors to resubmit corrected prescription drug event (PDE) records for the affected transactions.

In February 2015, as a result of the notification, Express Scripts responded to CMS that according to the Louisiana Pharmacy Benefits Management Services Manual, a $0.10 prescription fee is allowed on all prescriptions filled by the pharmacy.

> *A prescription fee shall be paid by each pharmacy and dispensing physician for each out-patient prescription (Medicaid and non-Medicaid) dispensed. The fee shall be $.10 per prescription dispensed by a pharmacist or dispensing physician. When a prescription is filled outside of Louisiana but not shipped or delivered in any form or manner to a patient in the state, no provider fee shall be imposed. However, out-of-state pharmacies or dispensing physicians dispensing prescriptions which are shipped, mailed or delivered in any manner inside the state of Louisiana shall be subject to the $.10 fee per prescription.*

Given this response from Express Scripts, CMS ruled that PDE records with sales taxes of $0.10 or less is allowed in the state of Louisiana. A letter was then sent to plan sponsors to discontinue the adjustment of the affected PDE records for the recoupment of sales tax.

On August 18, 2015, the Centers for Medicare & Medicaid Services (CMS) requested a summary of the deleted prescription drug event (PDE) records that were identified for plan sponsors. This request outlined the total difference between the original identified PDE records greater than $0.10 versus an updated analysis of the PDE records greater than $0.10. These PDE records were summarized by the total number of PDE records that were deleted by the plan sponsor for each contract by the contract year. This information was delivered to CMS on August 28, 2015.

On October 8, 2015, CMS requested an updated contract summary of original, identified PDE records having greater than $0.10 sales tax as of September 23, 2014 and deleted PDE records having greater than $0.10 sales tax as of June 17, 2015. In addition, CMS requested aanual spreadsheets containing PDE records by contract where the sales tax was greater than $0.10 on each PDE Record. CMS requested that the PDE records were limited to include only the key fields necessary to identify a unique PDE record. Based on guidance received from CMS regarding the key fields to uniquely identify a PDE record, the following seven fields were included:

- HICN
- Service Provider ID
- Service Provider ID Qualifier
- Prescription/Service Reference Number
- Date of Service
- Fill Number
- Dispensing status

A change in any of the above seven fields indicates a different event.

Methodology

Original PDE Records

Utilizing PDE records that were identified in the September 23, 2014 analysis as having a sales tax amount greater than $0.10, the total PDE record count, total paid amount, total sales tax amount and total billed amounts were calculated for each year by contract. Contract information reflects the current plan using the CMS Plan Crosswalk for 2014, which is the same original notification to plan sponsors. Only existing contracts and non plan-to-plan PDE records are included.

There were 75,883 PDE records identified with sales tax greater than $0.10 which were separated by claim year. These PDE records were separated by contract and limited to the seven key fields required to uniquely identify a PDE record.

Deleted PDE Records

Data extracted for analysis on June 17, 2015 were utilized to identify PDE records that were deleted as a result of the prior plan sponsor notification. The total PDE record count, total paid amount, total sales tax amount and total billed amounts were calculated for each year by contract. Contract information reflects the current plan using the CMS Plan Crosswalk for 2014, which is the same original notification to plan sponsors. Only existing contracts and non plan-to-plan PDE records are included.

There were 65,674 PDE records identified as deleted when compared to the original report which were separated by claim year. These PDE records were separated by contract and limited to the seven key fields required to uniquely identify a PDE record.

Analysis and Findings

As of September 23, 2014, plan sponsors submitted 75,883 PDE records with a sales tax greater than $0.10. As of June 17, 2015, 65,674 deleted PDE records were identified that had sales tax greater than $0.10.

The total PDE record count by year is reflected in Table 1.

Table 1. Original, Remaining, and Deleted PDE Record Count by Year for PDE Records Having Greater than $0.10 Sales Tax

Year	Original PDE Record Count as of September 2014	Remaining PDE Record Count as of June 2015	Deleted PDE Record Count as of June 2015
2010	50,835	5,134	45,701
2011	315	268	47
2012	244	229	15
2013	6,409	3,981	2,428
2014	18,080	597	17,483
Total	***75,883***	***10,209***	***65,674***

Original PDE Records

For the 75,883 PDE records having greater than $0.10 sales tax as of September 23, 2014, summaries (see Attachment A) were prepared to include the total PDE record count, total paid amount, total sales tax amount, and total billed amount for each year by contract.

For each year, the seven primary key fields, including the Health Insurance Claim Number (HICN), date of service, service provider identifier, service provider identifier qualifier, fill number, prescription/service reference number, and dispensing status of each PDE record, were listed for each contract in separate spreadsheets (see Attachments B through F).

Deleted PDE Records

For the 65,674 deleted PDE records having greater than $0.10 sales tax as of June 17, 2015, summaries (see Attachment G) were prepared to include the total PDE record count, total paid amount, total sales tax amount, and total billed amount for each year by contract.

For each year, the seven primary key fields, including the Health Insurance Claim Number (HICN), date of service, service provider identifier, service provider identifier qualifier, fill number, prescription/service reference number, and dispensing status of each PDE record, were listed for each contract in separate spreadsheets (see Attachments H through L).

Conclusions

In summary, the analysis identified sales tax of $493,565.73 associated with 75,883 PDE records having a sales tax greater than $0.10 as of September 23, 2014.

As of June 17, 2015, 65,674 PDE records with a sales tax greater than $0.10 were deleted from IDR. The total deleted sales tax amount associated with these records was $440,440.19.

Source Statement

Under the Medicare Part D Program, the Centers for Medicare & Medicaid Services (CMS) makes payments to Medicare Advantage Prescription Drug Plan (MA-PD) and stand-alone Prescription Drug Plan (PDP) sponsors on a monthly basis through estimated subsidy payments and, if required, at year-end as a result of the payment reconciliation process. The payment reconciliation process compares estimated subsidy payments made to plan sponsors throughout the year with the cost data submitted by MA-PD and PDP sponsors through prescription drug event (PDE) records and Direct or Indirect Remuneration (DIR) data to determine any residual payments required by CMS to MA-PD and PDP sponsors or by MA-PD and PDP sponsors to CMS. The reconciliation process relies on four major data sources: the sum of payments made to plan sponsors throughout the year, final updated plan enrollment, PDE records from MA-PD and PDP sponsors, and DIR.

Each time a beneficiary fills a prescription under Medicare Part D, an MA-PD or PDP sponsor must submit a summary record called the PDE record to CMS. PDE records are not the same as individual drug claim transactions but are summary extracts using CMS-defined standard fields. CMS stores the PDE records submitted by MA-PD and PDP sponsors in the Integrated Data Repository (IDR). MA-PD and PDP sponsors submit an original PDE record and may either adjust or delete PDE records submitted to CMS within the designated schedule. The records provided herein represent the latest iteration of the PDE records submitted by MA-PD and PDP sponsors and do not represent the complete adjudication history of drug claim transactions. The complete adjudication history of a drug claim transaction resides with the responsible MA-PD or PDP sponsor.

This report contains confidential Part D data, information, and/or analysis (hereinafter referred to collectively as "material") based on data and records made available to the NBI MEDIC by CMS. To the extent that this material contains or was developed through the use of data contained within the CMS's IDR, please be advised that the IDR database is updated periodically with new or revised data and PDE records. The material contained herein does not reflect IDR additions and revisions made after the material was pulled from the IDR database. Therefore, any newly run calculations/materials may differ from calculations/materials contained herein.

Restriction on Part D Data Only: This information is also consistent with the provisions of 42 U.S.C. §§1395w-115(f)(2), which permit HHS officers, employees, and contractors to use information submitted pursuant to section 1395w-115 for the purposes of, and to the extent necessary in carrying out 42 U.S.C. §1395w-115, which include payment-related oversight and program integrity activities, and for conducting oversight, evaluation, and enforcement under Title XVIII of the Social Security Act. Any use of this information by the Department of Justice (DOJ) will be limited to carrying out health oversight activities.

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ACLR Response to Duplicate Payment Questions

Exhibit 174

From: Sean Donaghy
To: Brown, Sonja J. \(CMS/CPI\)
Cc: Brandenburg, Sara M. \(CMS/CPI\); Chartier, Frank D. \(CMS/CPI\); Downs, Tanette N. \(CMS/CPI\); Kenya, Dominca \(CMS/CPI\); Newkirk, Delois J. \(CMS/CPI\); Tetkoski, Frank \(CMS/CPI\); Thomas, India M. \(CMS/CPI\); Christopher Mucke; cmendez@livanta.com; pdegele@livanta.com
Subject: RE: ACLR Response to Duplicate Payment Questions
Date: Thursday, February 27, 2014 6:35:08 PM
Attachments: 02.27.14 DP NAIRP RAC Response - Secured.pdf

Everyone, the attached document contains our response to the questions submitted for duplicate payments. The document contains sample PDE records and has been encrypted. I will forward the password in a subsequent email.

Sean Donaghy | Project Director | ACLR, LLC
38705 7 Mile Rd, Ste 251 | Livonia, Michigan 48152-3975 | (734) 744 - 4404 | (734) 744 - 4150 | * mailto:sdonaghy@aclrsbs.com

-----Original Message-----
From: Brown, Sonja J. (CMS/CPI) [mailto:sonja.brown@cms.hhs.gov]
Sent: Wed 2/19/2014 6:24 PM
To: Sean Donaghy
Cc: Brandenburg, Sara M. (CMS/CPI); Chartier, Frank D. (CMS/CPI); Downs, Tanette N. (CMS/CPI); Kenya, Dominca (CMS/CPI); Newkirk, Delois J. (CMS/CPI); Tetkoski, Frank (CMS/CPI); Thomas, India M. (CMS/CPI); Christopher Mucke; Chris Mendez (cmendez@livanta.com); Philip Degele (pdegele@livanta.com)
Subject: Duplicate Payment Response

Sean,

Please see CMS' response to the Duplicate Payment Walkthrough held on January 16, 2014. Feel free to contact us with any questions and/or comments that you may have.

Thanks,

Sonja

Date: February 27, 2014

Issue: Duplicate Payments

RAC recommended recovery audit type: Automated Review

Estimated Potential Recoveries: $4 million annually

Overview, Background, and History of the Special Study

1. Can we see the history of the proposal, specifically the documents mentioned by the RAC that are dated

    a. September 27, 2011
    b. February 15, 2013
    c. April 22, 2013
    d. July 10, 2013
    e. August 29, 2013?

    Please see attachments A-E, respectively.

2. Should the DVC review 100% of the results of the feasibility study which was finalized August 29, 2013, to help validate the proposal?

    Yes. While we do not believe that a review will assist the DVC in validating the proposal (the data submitted by the plans were contradictory and facially incorrect), we do believe that such a review will assist the DVC in understanding why certain decisions were made regarding changes to certain aspects of the originally submitted NAIRPs.

3. How were the three contracts selected for the special study? Was statistical sampling used? Were they intended to be representative of the universe of contracts or were they intended to be good candidates for duplicates?

    These contracts were selected by CMS. Please see Attachment F for communications regarding this issue.

4. Which three contracts were selected for the special study? What are their coverage and demographic characteristics?

H5698, S5884, and S5967 were selected for this review. We do not understand what is being requested with respect to coverage and demographic characteristics.

5. What data was sought from the plans contacted? What information was specifically requested in the RFI?

   The RFI stated "[D]ocumentation in support of or against the improper payments currently identified" were requested, no specific information was identified in the RFI. Please see Attachment G for the RFI provided by CMS.

6. What data was obtained from the plans who replied?

   Responses to the data request and related findings were returned by the plans in the original exception report format with additional fields added to individual PDE. These additional fields contained a description code indicating an assertion/explanation for each listed PDE. A summary of each plan's assertions are provided in Attachment H.

7. What follow-up efforts were made to obtain a reply from the one contract that failed to reply?

   No efforts were made to obtain additional documentation from this contract. Procedurally, the failure to provide documentation in a complex review results in an automated review (the contracts were not advised of their participation in a special study). As a practical matter, the duplicative payments identified for Contract H 5698 were deemed immaterial by the RAC for purposes of the study.

PDE Fields

8. The beneficiary is identified only by the PTAP_INS_CLAIM_NUM field. In the event there has been a typographical error in that field, should additional fields with demographic information for the beneficiary be checked, such as PTAP_RX_CARDHOLDER_ID, PTAP_PATIENT_DOB, PTAP_PATIENT_GENDER, and/or PTAP_BENE_LINK_KEY?

   Yes, the PTAP_RX_CARDHOLDER_ID[1] or PTAP_BENE_LINK_KEY could be used to identify additional potential duplicate payments (and/or confirm the legitimacy of HICN duplicates). We do not believe; however, that either PTAP_PATIENT_GENDER or PTAP_PATIENT_DOB fields will be of additional assistance as they are often improperly populated.

[1] *Please see the information provided in Attachment I as provided in our response to Question 9; a Cardholder ID may change.*

9. In the instances where the five PDE fields match, the RAC proposes to apply an "Allowable Days Elapsed" test to determine a duplicate. For any instance where the PTAP_FILL_NUM is not 0, is an "Allowable Days Elapsed" test needed to ensure that a duplicate payment has been made? If, for example, the second refill is being filled twice, should that automatically be considered a duplicate even if the "Days Elapsed" is greater than the "Allowable Days Elapsed"?

   No, but we can add additional protocols to reduce false negatives arising from the application of similar protocols for varying fill matches. As outlined in greater detail to our response for Question 13 below; service providers routinely reuse service reference numbers for multiple prescriptions. Because of this, targeting duplicate fills for fill numbers greater than 0 would result in the identification of duplicate PDE that arose from different prescriptions. We can; however, apply varying percentages to varying fill numbers to calculate a more accurate "allowable days elapsed". This will have a significant impact on decreasing sample error arising from false negatives and is easily accomplished.

10. Where the five proposed PDE fields match and the "PTAP_ADJ_DEL_CD" field is "R" for resubmission (and not "A" for adjustment), why is an "Allowable Days Elapsed" test needed to ensure that a duplicate payment has been made? If a second payment is being made on a resubmitted claim, should that be considered a duplicate even if the "Days Elapsed" is greater than the "Allowable Days Elapsed"?

    We can modify the NAIRP to address this issue; however, as outlined in our responses to questions 9 and 13, we would be unable to determine whether the resubmission was duplicative or was the result of another prescription that was properly deleted.

Mechanics

11. What information led to the elimination of long term care facilities, vaccinations, and mail order prescriptions from consideration for duplicate payments?

    These procedural changes were requested by CMS driven; our concurrence was limited to duplicates arising from charges associated with vaccination fees (duplicates arose from the separate charge occurring for the vaccination and the concomitant fee for administering the drug). As outlined in greater detail in our response to Question 13 below, the elimination of LTC facilities and mail order pharmacies from this review will create an audit design flaw where none previously existed.

    a. What was the instance of false positives involving those three payment areas, compared to other payment areas?

As a practical matter, no false positives were identified as a result of this review; as no supporting documentation was provided for these plan assertions, all payments would be deemed improper by law. This finding is supported by the response to the RFI for S5967. For example, the data supplied by the plan clearly indicate that individual PDE were updated from information found within S5967's internal databases; however, for the 1,685 PDEs protested under the e-box category supplied, only 30 records contained additional information in the "ORIG_CUSTOMER_LOCATION_DESC", ORIG_LEVEL_OF_SERVICE_DESC, and PTAP_LEVEL_OF_SERVICE_DESC fields. It is clear from the information provided, as well as that not provided, that S5967 made claims that were not otherwise supported by its own records. As outlined in greater detail in our response to Question 13 below; insufficient, or lack of, documentation is considered improper by law. As no information was provided, each payment is improper.

As shown in Attachment H, S5884 reported a 17.85% ratio of LTC related PDE and 41.91% ratio of mail order pharmacy related PDE to total PDE selected; S5967 reported LTC and mail order ratios of 63.07% for LTC and 0.51% for mail order related PDE.

b. What was the instance of false negatives involving those three payment areas, compared to other payment areas?

This cannot be adequately calculated due to the lack of sufficient documentation available; however, the use of an "allowable days elapsed" calculation, as discussed in additional detail in our response to Question 10, will result in duplications that will not be selected. Elimination of LTC and mail order related PDE; however, will increase the sample design error to that amount equal to duplicate payments occurring in each payment area.

12. What specific edits, involving what specific fields of the PDE or other document, are employed to eliminate long term care facilities, vaccinations, and mail order prescriptions from consideration for duplicate payments? In other words, how do the edits work?

As initially proposed, the taxonomy codes for LTC facilities and mail order pharmacies would be identified from NPPES and applied to the service provider field of both the original and duplicative PDE records identified as duplicative. However, subsequent CMS communications indicate a "more accurate" determination may be made from the IDR and we will update the NAIRP to address this during the revision process. For vaccinations, we would conduct an additional review of the PTAP_VAC_ADMIN_FEE field to determine whether the duplicate PDE record arose as a result of a vaccination fee charge.

13. How was the 50% figure, used in the calculation of the "Allowable Days Elapsed," derived? For example, are there any preliminary data or studies that show a statistical probability that any prescription refilled within the first 50% of the "Days Supply" is a duplicate?

The decision to implement an additional process to calculate "Allowable Days Elapsed" was our attempt to apply a "reasonableness" standard to limited and improperly submitted datasets.

Background:

As a federal entity, CMS is required to identify overpayments "when an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation". For this issue, we have to balance the law against the likelihood that facially duplicative PDE are, in fact, overpayments. For example, when we executed our originally proposed audit methodology matching CMS guidance, which stated "in the majority of cases, the concatenation of Service Provider, Prescription/Service Reference Number and Fill Number uniquely identify a prescription", to the PDE data, we identified over 26 million duplicates prior to terminating the reports. In this case, a strict application of CMS guidelines and federal law would require that each of these payments be identified as improper and recovered. It was clear after reviewing the data; however, that many of the selected duplicate records were likely the product of a misunderstanding between CMS desire to uniquely identify prescriptions and the plans' understanding of what constituted a unique PDE; otherwise, CMS would not have believed that the concatenation of these 3 fields would typically result in a unique prescription. It was also clear that the PDE data were improperly submitted to CMS. For example, the original fill on a PDE was not always submitted as "0". Based on plan responses to the special study, it now seems apparent that there is no way to distinguish a refill from a previous fill either (early refill edits where both fill numbers match). Ultimately, we determined that despite the need to comply with CMS guidelines and federal law regarding recoveries, that our originally proposed methodology would result in the identification of duplicative PDE that were not, in fact, duplicative but rather the result of improper submission guidelines and inaccurate reporting by the plans. The PDE data provided for H5698 in Attachment 1 illustrate some of the problems that arise when reviewing for duplicative payments. As can be seen in the sample data, the same service reference number was used for multiple prescriptions, for two separate contracts, two separate service providers (NPI vs. NCPDP), and the same or multiple fills. It was for these reasons that we developed an audit protocol that would instill a measure of reasonableness into the process.

Application of an "Allowable Days Elapsed" Methodology:

To accomplish the reasonableness objective, we adopted a macro approach that considered the effects of the bid approval process and contrasted it against that of final reconciliation. For example, each plan has refill protocols, which are typically applied at 75% - 80% of days supply for a particular drug/prescription. In the strictest sense, no drug should be refilled (unless an authorized override has occurred) prior to that time. As anticipated drug costs are the primary component of the bid approval process and refill protocols are an integral part of determining annual drug cost and there is no information within the PDE indicative of authorized overrides, we determined that the cleanest approach to identifying duplicative payments was to apply a refill methodology to the exact match protocols we had previously developed. In this manner, we could eliminate many of the duplicative PDE derived from the limitation of the PDE data and the improper submission of that data by the plans. As such, we developed an "early refill methodology" and proposed to CMS a limited one-year automated review of duplicate payments that compared an "Allowable Days Elapsed" methodology calculated as 25% of "Days Supply" of the original PDE to the difference between the dates of service for PDE determined to be duplicative during the exact match process. A one-year review was selected to determine whether additional information could be derived from the PDE; our primary focus was on the PTAP_RX_CLAIM_NUM field; 25% was selected to eliminate the possibility that non-duplicative PDE would be selected (for example, over 52% of the original PDE were for a 30 day supply; the likelihood that a refill would be permitted within one week for these PDE was deemed a rare event). This proposal ultimately resulted in a "special study" implemented as a complex review for three contracts.

Special Study Feedback:

Unfortunately, the only quantifiable feedback we received from the plans was that duplicative PDE arising to an additional vaccination fee must also be removed. Under current processes, the plan's failure to provide any documentation during the special study would result in the immediate commencement of the automated review process and the issuance of a notification letter.

We also learned that it would be possible to eliminate additional false positives arising from the identification of emergency box fills for those duplicates that arise when less than a three day supply is filled for a LTC facility. While not as specific as that for vaccination fees, this additional step could be accomplished without significantly increasing design flaw false negatives.

Analysis of S5967: There are numerous problems associated with this plan's response to the RFI and it is immediately apparent that either there are significant differences between the data residing in their systems and that submitted to CMS or

they fabricated their responses. An example of this is the plan's claim that 602 claims (12.8% of total PDE selected) were not duplicative. To support its contentions, the plan stated the duplicative PDE were the result of their compliance with CMS guidelines and federal law by relaxing "refill edits" in major disaster areas. When reviewing the submitted data more closely; however, we noted that 581 of the "refills" had an original fill of "0" (indicative of a new prescription) and 501 of the prescriptions were for a different dosage than the original fill amount (indicative of a level of care change). The plan also did not provide any supporting documentation or explanation as to why these "refills" occurred so quickly after the initial fill was completed. This was also supported by the plan's contentions that selected PDE were the result of "vacations", which also consisted of "different dosages" and identical fill numbers.

We also believe that the plan inadvertently provided data that undermined its own contentions. As discussed in our response to Question 11a for example, in reviewing transactions for its "e-box" contentions, it is immediately apparent that some of the fields were populated with data from its own systems. The additional fields contained information related to the customer location and a level of service description. Of these fields, only 30 of the 1,685 PDE listed contained information lending support to its claims; the remaining fields were blank indicating that no such information was available in their systems. In addition, another field indicated that 20 PDE were "no e-box" while another indicated that 306 PDE were for different dosages than the originally prescribed medication. Further, the plan's contentions that a legitimate "dosage change" occurred was undermined when another field indicated that that the "same dosage" was administered. In short, the information received from this plan was not credible.

Analysis of S5884: S5884 did not provide any documentation its contentions and some of its responses were suspicious; however, the information submitted facially more plausible than that submitted by S5967. While some anomalies exist and questions arose with comments such as "appear to be" and claims "submitted with a Pharmacy Submitted Override Code", additional reviews (the service provider listed under a LTC reason code was for a LTC facility) did not contradict the data supplied. As with S5967 above, the plan did not provide any explanation as to why a drug that received a "prior authorization" was submitted twice.

Selection of 50%

As outlined above, and to inject a measure of reasonableness to the identification of improper payments, we adopted a methodology to eliminate duplicative PDE submitted as a result of improper design and submission errors. Strictly speaking, the bid approval process, CMS guidelines, and federal law regarding the identification of improper

payments requires that we adopt a strict application of each plan's refill protocols would be the most correct course of action. Based on our experience in similar audits; however, we've learned that as we approach the "75% - 80%" threshold, the identification of legitimate duplicates decreases. As noted in previous proposals, our experience in similar audits indicates that a 60% allowable refill methodology is that point where we maximize refunds and minimize administrative burdens (diminishing returns). We've proposed 50% as a means to implement a fair and unimpeachable approach.

14. If a person loses his prescription bottle and gets a refill well before the expected refill date (that is, within the first 50% of the "Days Supply"), is it likely that this will be considered an improper duplicate?

Yes, this would be considered a legitimate duplicate identified as a result of insufficient population of data (as opposed to an audit design flaw).

15. If a person is expecting to take a long trip out of the country and wants to stock up on a prescription drug before leaving, will an early refill (that is, within the first 50% of the "Days Supply") be considered an improper duplicate?

No, the proposed duplicate payment process does not target "early refills". The process is designed to target duplicate payments arising from duplicative PDE submissions; an "early refill" methodology is applied solely to eliminate the identification of multiple prescriptions containing identical characteristics. In the case of a true "early refill" arising in the scenario provided, the fill number would be different than the preceding fill and would not be selected as duplicative.

16. What constitutes a "transition from a retail pharmacy to a mail order pharmacy" and how is it determined? Specifically, what fields of the PDE or other document are utilized to make this determination?

This scenario arose out of the responses from the plans during the special study and has been eliminated at CMS' request; the RAC does not concur with this recommendation as it creates a design error where none previously existed (duplicate payments arising from duplicative "retail/mail order transitions" will not be captured). As initially proposed and outlined in our response to Question 12 above, the taxonomy codes for retail and mail order pharmacies would be identified from NPPES and applied to the service provider field of both the original and duplicative PDE records identified as duplicative. However, subsequent CMS communications indicate a "more accurate" determination may be made from the IDR and we will update the NAIRP to address this during the revision process.

17. Why are PDEs that result from a transition from a retail pharmacy to a mail order pharmacy eliminated? What facts indicate that these situations result in more false positives or false negatives than other duplicates found through the matching criteria proposed?

As noted in our response to Question 16 above, this part of the process has been incorporated at CMS' request. Interestingly, the results from the special study are inconsistent across plans; in the case of contract S5967, only 0.51% of selected PDE were for "pending mail order" PDE while nearly 42% of those selected for Humana were for similar transactions. From an audit design standpoint, this disparity alone militates against its exclusion.

18. If the original prescription is filled by a brand name drug and the subsequent (potential duplicate) prescription is filled by a generic drug or vice versa, how can the RAC process be modified to identify this type of duplicating scheme?

Our focus has been on the identification of PDE containing duplicative characteristics (such as the duplicative billing for an identical NDC) rather than for those that may be more therapeutically duplicative (different NDC or drug classifications). From a design standpoint we would similarly classify the NDCs for brand name/generic drugs and apply the remaining methodology to matching PDE.

Results

19. For S5967, there is often a disparity between the original and "duplicate" PTAP_QUANTITY_DISPENSED and original and "duplicate" PTAP_DAYS_SUPPLY. Do you believe these differences should play a role in determining whether the claims are duplicates? Could these differences result from to "partial" fills that were not been properly coded as such, rather than duplicates?

These differences could have arisen as a result of improperly submitted partial claims; improperly submitted fill amounts (1 unit of 30 versus 30 units); as well as dosage or prior authorizations as intimated by the plans.

20. For S5967, what do the values in the last column (Claim Response) on the last page represent?

These are assertion "categories" by which the plan intends to support its contentions that no duplicate payments were made. The description key for S5967 and for that of S5884 are included in Attachment H as outlined in our response to Question 6 above.

21. Are all of the paired results on all of the S5884 and S5967 pages considered non-allowable duplicates?

Yes.

22. Why are the PDE sample results for S5884 and S5967 so different? S5967 contains many of the matching of the various fields and components of the calculations but S5884 does not.

The PDE submitted in the RFI were manipulated by the plans; the information provided including the data fields not typically appearing in exception reports were provided as submitted by the plans.

23. The results for S5967 show only the "Days Elapsed" and not the "Allowable Days Elapsed," or the "Days Elapsed Less Than Allowable Days Elapsed" as described in the RAC's proposal? Can those be obtained?

As outlined in our response to Question 22, these data were provided by the plans. CMS can provide the original and duplicate PDE identified by the RAC and submitted to the plans in the original RFI.

24. Were any PDEs from non-standard sources reviewed as discussed in the RAC's proposal, and, if so, what were the additional reviews conducted other than the automated review? What results were found?

We did not conduct that review for this study; all records regardless of information listed in the "non-standard" field were included. Based on our preliminary reviews of this field for other contracts; however, we see a much higher percentage of likely duplication when a paper record has been input than when not.

25. The last paragraph of the RAC proposal states that partial PDE records and findings from the special study have been submitted with the NAIRP. How were the submitted records selected from the total records? Was statistical sampling used? What percentage of the total records do the submitted records represent?

In an attempt to eliminate cumbersome record submissions during the NAIRP process, we selected the 1st 100 records of the spreadsheet submitted back to us by the plans; no additional review was considered in the selection. The original duplicate PDE identified for S5967 was 4,703 records and 23,610 records for S5884.

26. With the two attached samples the RAC has paired the duplicated PDEs. For the actual audit will the RAC be providing the individual PDEs so the DVC can independently validate the potentially duplicated PDEs?

Yes, both the original and duplicative records will be provided.

27. Please confirm that the estimate for recoveries ($4M annually) is the estimate for all Part D contracts for one year?

This estimate was derived as a result of a national average of 0.1% resulting from duplicate payments, the application of plan findings (Contract S5884 assertions were used), and the assumption plans would submit documentation supporting its contentions in accordance with the law.

28. The predominate response from the plan sponsors may be that an early over-ride preauthorization was granted. If so, what documentation will be acceptable to verify this not a duplicate?

A copy of the prior authorization form, indicative of a legitimate override, would be deemed compliant and verification that a PDE was not duplicative.

29. Given the RFI responses from the duplicate payment pilot conducted in the summer of 2013, how was the decision made to conduct an automated review vs. a complex review?

As shown in the attachments provided in our response to Question 1, this review has always been considered an automated review; a complex review was conducted solely to comply with CMS' request to conduct a special study. There is no accounting/auditing reason to support a complex review.

Affidavit II of Christopher Mucke

Exhibit 175

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

ACLR, LLC	)	
	)	
Plaintiff	)	
	)	
v.	)	**Civil Action No. 15-767 and 16-309**
	)	(Judge Campbell-Smith)
THE UNITED STATES	)	
	)	
Defendant	)	
	)	

AFFIDAVIT OF CHRISTOPHER MUCKE IN SUPPORT OF PLAINTIFF ACLR'S REPLY IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AND RESPONSE TO DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

I, Christopher Mucke, am competent to testify on the matters stated herein and make the following statements on personal knowledge and under oath:

1. I am the Managing Principal of ACLR, LLC and am over 18 years of age.

2. ACLR, LLC is recovery auditing firm whose clients have included the Centers for Medicare & Medicaid services, state governments and some of the largest manufacturing, automotive, pharmaceutical, and aviation companies in the world.

3. I have over 30 years of recovery audit experience including federal and state statutory and regulatory payment compliance; data analysis; statistical sampling; and litigation support services with a particular emphasis in prescription drug benefit and federal, international, and state sales, use, excise, and value added taxation payment recoveries. I am a graduate of the University of Tennessee, Chattanooga and a former Certified Public Accountant, licensed in Maryland. I have been a guest lecturer at numerous business organizations and the Georgia

Institute of Technology and have authored or co-authored white papers and articles on statutory compliance and statistical sampling recovery audit methodologies.

4. I discussed with CMS the potential for the recovery of duplicate payments including those for PY 2007 on multiple occasions after January 2012.

5. ACLR initially proposed that the 2009-2012 duplicate payment audit be conducted as an automated audit.

6. 90% of the plan sponsors failed to provide any documentation in response to ACLR's PY 2010 duplicate payment requests for information.

7. ACLR conducted its own analysis of the Minnesota PDE records comparing the amount in the sales tax field with the amount in the ingredient cost field.

8. Over 90% of the PY 2012-2013 Minnesota PDE records in ACLR's sales tax NAIRP and the Minnesota PDE records covered by the ACLR II Complaint have amounts billed in the sales tax column at 2% or higher than the ingredient cost paid.

9. The ingredient cost paid represents the retail price charged by pharmacies and would be greater than the wholesale drug cost which is taxed at 2% so the sales tax field is incorrect even if the wholesale drug tax could be included in the sales tax field and billed at 2% of the wholesale drug cost, which it cannot.

10. As of September 10, 2015, CMS had rescinded or denied 100% of all the NAIRPs ACLR had submitted to CMS for approval.

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this 6th day of July, 2018 at NOVI, MICHIGAN

Christopher Mucke

STATE OF MICHIGAN
COUNTY OF OAKLAND, To-wit:

This foregoing instrument was acknowledged before me this 6th day of JULY, 2018 by CHRISTOPHER MUCKE.

Notary Public
Notary Number
My commission expires: OCT. 13, 2024

MARILYN S. TROUTMAN
NOTARY PUBLIC, STATE OF MI
COUNTY OF OAKLAND
MY COMMISSION EXPIRES Oct 13, 2024
ACTING IN COUNTY OF OAKLAND

June 19, 2013 Email

Exhibit 176

From: Brown, Sonja J. (CMS/CPI)
Sent: Wednesday, June 19, 2013 5:32 PM
To: Chartier, Frank D. (CMS/CPI)
Subject: DRAFT PI - Part D RAC 6 17 13.docx
Attachments: DRAFT PI - Part D RAC 6 17 13.docx

Frank,
Here are my responses. Can we chat when you have a chance?

Thanks,

Sonja

Q. Is the Part D RAC up and running?

A. Yes, the Part D RAC contract was awarded to ACLR Strategic Business Solutions in January of 2011. It is has been fully operational since last year and has already completed its first audit review of excluded providers for plan year 2007.

Q. What is the Part D RAC currently investigating?

A. CMS has identified three audit areas that the RAC will initially focus on:

1. Excluded providers,
2. Direct and Indirect Remuneration (DIR), and
3. Duplicate PDEs.

The Part D RAC contractor has finished its Excluded Provider Audit Review for the 2007 plan year and plan sponsors affected by the audit have been notified of the results. For the next audit, the Part D RAC has initiated its review of excluded providers for plan years 2008 & 2009.

Additional audit topics may be proposed to reflect the recent results of studies that have been highlighted as problem areas by the HHS Office of the Inspector General and the U.S. Government Accountability Office.

The Part D RAC refers any potential fraud findings identified during the auditing process to the Medicare Drug Integrity Contractor (MEDIC).

Q. How much money has the Part D RAC been able to recover?

A. The RAC has collected $1.8 million so far.

Q. That doesn't seem like very much, especially when compared to the FFS RAC. Why so little?

A. The Part D RAC program is a new program that is just beginning to finish some of their first audit areas. As the program matures and more audit areas are added, we expect the recoveries to grow. That's the way the RAC program worked in FFS, and that's the way we hope the Part D RAC program will also work.

Consider:

Recovery audits performed on Medicare Part D identify and collect on Medicare's impact on improperly paid Prescription Drug Events (PDEs). There are many payers in the Part D Program: Beneficiary, Plan, CMS; and now drug manufacturing companies, and each can share the impact of an improperly paid PDE. Depending on what status

the beneficiary is and where they are in a specific plan benefit package, this amount can change and impact each of these payers accordingly. CMS is only reporting on Medicare's determined impact and recovered amount. Also, prescription drug medication is much cheaper than services you'd see being paid for within FFS. The combination of these two reasons, along with the RAC program being in its infancy stage, has led to the amount of recoveries reported.

Q. What are your future plans for the Part D RAC?

A. Additional audit topics may address problem areas identified by the HHS Office of the Inspector General and the U.S. Government Accountability Office.

Q. How do you avoid duplicative work between the MEDIC and the RAC?

A. The responsibilities of the MEDIC and the RAC are separate. The MEDIC has the following responsibilities:

- Managing all incoming complaints about Part C and Part D fraud, waste, and abuse;
- Using new and innovative techniques to monitor and analyze information to help identify potential fraud;
- Working with law enforcement, MA and prescription drug plans, consumer groups, and other key partners to protect consumers and enforce Medicare's rules; and Identifying program vulnerabilities.

The Part D RAC is tasked to identify underpayments and overpayments and recoup overpayments. The Part D RAC refers any potential fraud findings identified during the auditing process to the MEDIC.